# In the United States Court of Federal Claims Office of special masters

CHRISTOPHER DEMORE, \* Petitioner, No. 20-1265V Special Master Christian J. Moran v. \* Filed: September 26, 2024 \* SECRETARY OF HEALTH \* AND HUMAN SERVICES, \* Respondent. 

<u>Leah V. Durant</u>, Law Offices of Leah V. Durant, Washington, DC, for petitioner; <u>Julianna Rose Kober</u>, United States Dep't of Justice, Washington, DC, for respondent.

## **DECISION DENYING COMPENSATION**<sup>1</sup>

Christopher Demore alleges that an influenza ("flu") vaccine caused him to suffer a neurologic condition, myasthenia gravis. He supported his claim by presenting reports from two experts, David Simpson (a neurologist) and Ronald Simon (a specialist in internal medicine and immunology). The Secretary opposed an award of compensation. The Secretary also relied upon reports from two experts, Mark Bromberg (a neurologist) and Marcela Pasetti (a Ph.D. immunologist, who is not a medical doctor). After the parties developed their evidence, the parties advocated through briefs.

<sup>&</sup>lt;sup>1</sup> Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <a href="https://www.govinfo.gov/app/collection/uscourts/national/cofc">https://www.govinfo.gov/app/collection/uscourts/national/cofc</a>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

Mr. Demore has not demonstrated that he is entitled to compensation. He has not presented a persuasive theory by which the flu vaccine can cause myasthenia gravis.

## I. Events in Mr. Demore's Medical History<sup>2</sup>

Mr. Demore was born in 1951. Exhibit 11. Around the time of vaccination, he worked as cook at a retreat center. Exhibit 12 (damages affidavit)  $\P$  5. Although Mr. Demore had some health problems before the vaccination, these pre-existing conditions are not relevant to present decision.

Mr. Demore received a flu vaccine on October 2, 2018. Exhibit 1 at 2. He alleges this vaccination caused his subsequent myasthenia gravis.

Mr. Demore developed diplopia (double vision) on October 18, 2018. Exhibit 6 at 2952. After the diplopia continued for two days, Mr. Demore sought care at an emergency department. Exhibit 7 at 4. The doctor admitted Mr. Demore to the hospital. He stayed for a few days and was discharged. Mr. Demore saw multiple medical professionals both inside and outside a hospital.

Eventually, doctors ordered tests for antibodies suggestive for myasthenia gravis. See Exhibit 7 at 12. Mr. Demore was found to have ACH receptor binding antibodies. Exhibit 2 at 51. A doctor at Duke Health, Firas Chazli, stated that "positive ACH receptor binding antibodies [are] suggestive of myasthenia gravis." Exhibit 5 at 80. In the context of this litigation, the parties' retained experts agree that the appropriate diagnosis is myasthenia gravis. See Exhibit 14 (report of Dr. Simpson) at 3; Exhibit A (report of Dr. Bromberg) at 6.

The remaining medical records chart the ebbs and flows of Mr. Demore's myasthenia gravis. Mr. Demore also described in an affidavit how the condition has affected his life. Exhibit 47.

## II. Procedural History

The course of Mr. Demore's case is straightforward. He initiated the case by filing the petition on September 24, 2020. He filed medical records.

2

<sup>&</sup>lt;sup>2</sup> Because the critical issue--whether the flu vaccine can cause myasthenia gravis--is a general question, Mr. Demore's medical history is summarized. For more detailed accounts, <u>see</u> Pet'r's Br., filed Jan. 3, 2024, at 2-11; Resp't's Br., filed Mar. 18, 2024, at 2-11.

Mr. Demore was directed to identify any treating doctors who linked his flu vaccine to his myasthenia gravis. Mr. Demore forthrightly recognized that there were no examples. Pet'r's Status Rep., filed Feb. 1, 2021. Because Mr. Demore was likely to seek a report from an expert, a set of instructions was issued on February 3, 2021.

The Secretary advised that compensation should not be awarded. Resp't's Rep., filed Mar. 3, 2021.

The parties submitted a series of reports from their experts. Each expert wrote two reports--Dr. Simpson (Exhibits 14 and 43), Dr. Simon (Exhibits 40 and 44), Dr. Bromberg (Exhibits A and E), and Dr. Pasetti (Exhibit C and F).

The next step was for the parties to argue their cases. Order, issued June 29, 2023. Mr. Demore's primary brief was filed on January 3, 2024 and his reply brief was filed on April 17, 2024. In between, the Secretary filed his brief on March 18, 2024.

Mr. Demore's case can be adjudicated on the papers. Because both parties have had a fair opportunity to present their evidence and their arguments, an adjudication based upon the papers is appropriate. See Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

## III. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

Petitioners bear a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

#### IV. Analysis

The dispositive prong is the first <u>Althen</u> prong, which concerns the medical theory. Mr. Demore proposes molecular mimicry. Pet'r's Br. at 13.<sup>3</sup> However, at the appropriate level of scrutiny, Mr. Demore's evidence is not persuasive to establish that this theory is reliable.

#### A. Appellate Cases Involving Molecular Mimicry

Because special masters are often called upon to evaluate the persuasiveness of the theory of molecular mimicry, the Court of Federal Claims and the Court of Appeals for the Federal Circuit have considered molecular mimicry in their appellate role opinions from special masters. In December 2019, the undersigned identified the leading precedents as W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352 (Fed. Cir. 2013), and Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff'd sub nom., 463 F. App'x 932 (Fed. Cir. 2012). Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at \*12-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020). While Tullio describes those cases in more detail, their essence appears to be that although molecular mimicry is accepted in some contexts, special masters may properly require some empirical evidence to show that a particular vaccine can cause a particular disease.

In the next approximately four years, appellate authorities reviewing decisions involving molecular mimicry have generally endorsed the approach of looking for some evidence that persuasively shows that a portion of a vaccine

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<sup>&</sup>lt;sup>3</sup> Dr. Simpson's report mentioned other theories, such as neurotoxic effect of vaccines and immune complex formation. Of this group of theories, molecular mimicry appeared to be the most developed. See Exhibit 14 at 4. As part of the order for briefs, Mr. Demore was directed to put forward "complete and cogent arguments." In response, Mr. Demore advanced only the theory of molecular mimicry. See Pet'r's Br. at 13-17; Pet'r's Reply at 2-5. Thus, only molecular mimicry is discussed in this decision.

resembles a portion of human tissue, which contributes to causing the disease, and that the immune system will respond to the relevant amino acid sequence.<sup>4</sup> Chronologically, the list of more recent appellate cases begins with the opinion in Tullio, which denied the motion for review. 149 Fed. Cl. 448, 467-68 (2020).

Another example in which the Court of Federal Claims held that the special master did not elevate the petitioner's burden of proof in the context of evaluating the theory of molecular mimicry is Morgan v. Sec'y of Health & Hum. Servs., 148 Fed. Cl. 454, 476-77 (2020), aff'd in non-precedential opinion, 850 F. App'x 775 (Fed. Cir. 2021). In Morgan, the Chief Special Master found that petitioner had not presented persuasive evidence about a relevant antibody. Id. at 477. The Chief Special Master also noted that the articles about the relevant disease do not list the wild flu virus as potentially causing the disease. Id. When examining this analysis, the Court of Federal Claims concluded: "the Chief Special Master did not raise the burden of causation in this case; petitioner simply failed to meet it." Id.

The Federal Circuit also evaluated the Chief Special Master's approach in Morgan. The Federal Circuit concluded: "We discern no error in the special master's causation analysis." 850 F. App'x 775, 784 (Fed. Cir. 2021).

Most other recent appellate cases follow this path. See, e.g., Duncan v. Sec'y of Health & Hum. Servs., 153 Fed. Cl. 642, 661 (2021) (finding the special master did not err in rejecting a bare assertion of molecular mimicry); Caredio v. Sec'y of Health & Hum. Servs., No. 17-79V, 2021 WL 6058835, at \*11 (Fed. Cl. Dec. 3, 2021) (indicating that a special master did not err in requiring more than homology and citing Tullio); Yalacki v. Sec'y of Health & Hum. Servs., 146 Fed. Cl. 80, 91-92 (2019) (ruling that special master did not err in looking for reliable evidence to support molecular mimicry as a theory); but see Patton v. Sec'y of Health & Hum. Servs., 157 Fed. Cl. 159, 169 (2021) (finding that a special master erred in requiring petitioner submit a study to establish medical theory causally connecting flu vaccine to brachial neuritis).

The Court of Federal Claims explained why petitioners must present some evidence to show the persuasiveness of molecular mimicry as a theory in their cases. <u>Dennington v. Sec'y of Health & Hum. Servs.</u>, 167 Fed. Cl. 640 (2023), appeal dismissed, No. 2024-1214 (Fed. Cir. Mar. 25, 2024). There, Ms.

<sup>&</sup>lt;sup>4</sup> The term "homology" is used when discussing molecular mimicry. "Homology" is defined as "the quality of being homologous; the morphological identity of corresponding parts; structural similarity due to descent from a common form." *Dorland's* at 868.

Dennington alleged that a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine caused her to develop GBS. <u>Id.</u> at 644. She supported her claim with two reports from a neurologist, Carlo Tornatore, who put forward molecular mimicry. <u>Id.</u> at 647-49. The chief special master denied entitlement. Id. at 656.

Because the chief special master did not commit any error in evaluating Ms. Dennington's prong one evidence, the Court of Federal Claims denied a motion for review. The Court emphasized the lack of evidence supporting Dr. Tornatore's opinion:

- "While Petitioner and Dr. Tornatore put forth the well-established medical theory of molecular mimicry as the mechanism through which the Tdap vaccine could cause GBS, nowhere in Dr. Tornatore's expert reports, nor in Petitioner's briefs, do they specifically tie the Tdap vaccine to GBS through molecular mimicry." <u>Id.</u> at 653.
- "Dr. Tornatore never actually explains how molecular mimicry might occur from the Tdap vaccine specifically, nor does he elaborate on how molecular mimicry could cause the specific autoimmune system reaction that could cause GBS." <u>Id.</u>
- "There is nothing in Dr. Tornatore's report that explains or even alludes to what antigens or structures in the Tdap vaccine could share homology with possible host antigens and how these antigens could react in the manner GBS is believed to progress." Id. at 654.
- "The literature upon which he relies make no mention of any causal connection between GBS and the Tdap vaccine." <u>Id.</u>

Based upon these observations, the Court criticized the lack of specificity in Dr. Tornatore's opinions:

In fact, because Dr. Tornatore does not offer any specific explanation as to the distinct connection between Tdap, molecular mimicry, and GBS, one could take Dr. Tornatore's causation theory and substitute any table vaccine (e.g., the measles vaccine) and any autoimmune disorder (e.g., autoimmune encephalitis) and Dr. Tornatore's expert report's discussion of molecular mimicry would require absolutely no changes. That is how general his molecular mimicry theory is—it does not

matter which vaccine and which autoimmune disorder are plugged in. But *Althen* prong one requires more.

Id.

In accordance with precedents such as <u>W.C.</u>, <u>Caves</u>, <u>Tulio</u>, <u>Yalacki</u>, and <u>Dennington</u>, the undersigned will look to see whether any evidence supports the theory that flu vaccine can cause CIDP.

# B. Evidence regarding Molecular Mimicry<sup>5</sup>

Preliminarily, some evidence persuasively shows that scientists sometimes propose molecular mimicry as a method to explain how autoimmune diseases might develop. Examples of articles about molecular mimicry in general include Levin and Bach.<sup>6</sup> The idea of molecular mimicry as a general concept is not contested. What is challenged is whether Dr. Simpson and Dr. Simon have applied the theory in the context of a flu vaccine and myasthenia gravis. <u>See</u> Resp't's Br. at 32.

Here, relatively little direct evidence supports a causal link between the flu vaccine and myasthenia gravis. One epidemiological study explored how people with myasthenia gravis responded to receiving the flu shot. The authors determined that the flu vaccine was not associated with an increase in myasthenia gravis symptoms. Zinman at 950. <sup>7</sup> This article tends to undermine the persuasiveness of a claim that the flu causes myasthenia gravis.

<sup>5</sup> In accordance with the previous directive, this decision focuses upon the articles that the parties have cited in their briefs. Order for Briefs, issued June 29, 2023, at 6.

<sup>6</sup> Michael C. Levin et al., <u>Neuronal Molecular Mimicry in Immune-Mediated</u> <u>Neurologic Disease</u>, 44 ANN. NEUROL. 87 (1998); filed as Exhibit 17.

Jean-Francois Bach, <u>The etiology of autoimmune disease: the case of myasthenia gravis</u>, 1274 ANN. N.Y. ACAD. Sci. 33 (2012); filed as Exhibit 24.

<sup>7</sup> Lorne Zinman et al., <u>Safety of influenza vaccination in patients with</u> myasthenia gravis: a population-based study, 40 MUSCLE NERV. 947 (2009); filed as Exhibit 36.

To attempt to reduce the evidentiary value of Zinman, Mr. Demore uses two techniques. First, he presents his own study whose outcome conflicts with the outcome in Zinman. For this purpose, Mr. Demore cites Sanghani.<sup>8</sup> Pet'r Br. at 16-17. Sanghani carries minimal weight for multiple reasons. Mr. Demore submitted only an abstract, not the whole article. The filing of an article is not in accord with the Instructions for reports from expert witnesses. Order, issued Feb. 3, 2021, at 8. Abstracts provide less information and, therefore, are difficult to assess. Kalajdzic v. Sec'y of Health & Hum. Servs., No. 17-792V, 2022 WL 2678877, at \*13 n.16 (Fed. Cl. Spec. Mstr. June 17, 2022), mot. for rev. denied in an unpublished opinion, (Fed. Cl. Oct. 27, 2022), aff'd 2024 WL 3064398 (Fed. Cir. 2024); see also Hazlehurst v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 473, 488 (2009), aff'd 604 F.3d 1343 (Fed. Cir. 2010).

Moreover, Sanghani attempted to draw conclusions from data contained in the Vaccine Adverse Events Reporting System ("VAERS"). Exhibit 42 at 2. But, this methodology has generally been found to be unsound. H.L. v. Sec'y of Health & Hum. Servs., 715 Fed. App'x 990, 995-96 (Fed. Cir. 2017); Analla v. Sec'y of Health & Hum. Servs., 70 Fed. Cl. 552, 558 (2006). Thus, the Sanghani article does not meaningfully support the proposition that the flu vaccine can cause myasthenia gravis.

The alternative way Mr. Demore attacks the Zinman article is to argue that as an epidemiologic study, the study is underpowered to detect a rare event, such as, according to Mr. Denmore, instances in which a flu vaccine caused myasthenia gravis. See Pet'r's Br. at 16. Mr. Denmore is not wrong abstractly. Tullio, 2019 WL 7580149, at \*10 (noting a larger study might find a risk undetected by smaller studies). But, special masters cannot resolve cases based upon what some future study might show. See Sharpe v. Sec'y of Health & Hum. Servs., 964 F.3d 1072, 1083 (Fed. Cir. 2020). The strongest study in the record of Mr. Demore's case is the Zinman article, which tends to point against a finding that the flu vaccine causes myasthenia gravis.

Although Zinman is a strong study because the authors considered the exact vaccine-injury combination (see Smilo v. Sec'y of Health & Hum. Servs., No. 18-1585V, 2023 WL 3918397, at \*40 (Fed. Cl. Spec. Mstr. May 15, 2023) (characterizing Zinman and two other articles as the "best evidence available on

8

<sup>&</sup>lt;sup>8</sup> Nirav Sanghani et al., <u>Myasthenia Gravis after Vaccination in Adults the United States: A Report from the CDC/FDA Vaccine Adverse Event Reporting System (1990–2017)</u>, 90 NEUROLOGY 15 Suppl. (2018); abstract filed as Exhibit 42.

the question of whether the flu vaccine can exacerbate myasthenia gravis"), Mr. Demore may establish his claim using indirect or circumstantial evidence. <u>Capizzano v. Sec'y of Health & Hum. Servs.</u>, 440 F.3d 1317, 1325 (Fed. Cir. 2006).

Circumstantial evidence includes evidence from which an inference might be drawn. For example, Mr. Denmore contends that because molecular mimicry could explain how the flu vaccine can cause one neurologic disorder (Guillain-Barré syndrome), molecular mimicry can explain how the flu vaccine can cause another neurologic disorder (myasthenia gravis). Pet'r's Br. at 13, 15.

Whether this reasoning by analogy is persuasive depends upon various factors. For example, how does the etiology of one disease (Guillain-Barré syndrome) compare to the etiology of the other disease (myasthenia gravis). See Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1365 (Fed. Cir. 2000) ("In order for the study to be instructive, however, its conclusions must fit the facts of the case under consideration."); R.V. v. Sec'y of Health & Hum. Servs., 127 Fed. Cl. 136, 142 (2016) ("advancing a similar theory under a different set of facts" does not necessarily satisfy Althen.); Drobbin v. Sec'y of Health & Hum. Servs., No. 14-225V, 2020 WL 3799206 at \*17 (Fed. Cl. Spec. Mstr. Jan. 21, 2020) (stating it is "logical to draw comparisons between the etiology of diseases that are so similar that doctors sometimes misdiagnose one for the other"). See also Resp't's Br. at 46.

However, neither Dr. Simpson nor Dr. Simon explains why Guillain-Barré syndrome is sufficiently similar to myasthenia gravis that the former can be used as a proxy for the latter. See Exhibit 14 (Dr. Simpson's report) at 5; Exhibit 40 (Dr. Simon's report) at 3; See also Exhibit A (Dr. Bromberg's report) at 6.

Another type of analogy is one in which the disease (myasthenia gravis) remains constant and the preceding event changes. Examples include articles purporting to link West Nile virus to myasthenia gravis and case reports about other vaccines and myasthenia gravis. Pet'r's Br. at 16, citing, among other exhibits, Leis. A primary difficulty to accepting an analogy between infections and non-live vaccines is that "virus[es] can replicate." Exhibit C (Dr. Pasetti) at 4. An infection "can cause overt disease and compromise overall health, while this is not the case with vaccines." Id. at 4-5. Furthermore, some of the articles involving

<sup>&</sup>lt;sup>9</sup> A. Arturo Leis et al., <u>West Nile Virus Infection and Myasthenia Gravis</u>. 39 MUSCLE NERVE 26 (2014); filed as Exhibit 25.

vaccines (other than flu vaccine) and myasthenia gravis are case reports. <u>E.g.</u>, Eddy, Hung, Biron, Valerie, Bahri, and Chung.<sup>10</sup>

In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which the vaccination preceded an adverse health event. See K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at \*11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports); C.f. Stricker v. Sec'y of Health & Hum. Servs., 170 Fed. Cl. 701, 714 (2024) (noting that petitioner did not challenge the special master's determination that case reports merit little weight).

A final category of analogies includes examples in which neither the preceding event is the flu vaccine nor the studied disease is myasthenia gravis. For example, Mr. Demore reasons that because the Covid vaccine has been associated with some neurologic diseases, then the flu vaccine should be similarly associated

Hung et al., <u>HIV-associated myasthenia gravis and impacts of HAART: One case report and a brief review</u>, 113 CLIN. NEUROL. NEUROSURG. 672 (2011); filed as Exhibit 28.

Pierre Biron et al., <u>Myasthenia Gravis After General Anesthesia and Hepatitis B Vaccine</u>, 148 ARCH. INTERN. MED. 2685 (1998); filed as Exhibit 32.

Domingo Valerie et al., <u>Should Hepatitis B Vaccine be Contra-indicated in Myasthenia Gravis?</u>, 29 AUTOIMMUNITY 139 (1998); filed as Exhibit 33.

ME Bahri et al., <u>Myasthenia Gravis After Hepatitis B Vaccine. Report Of One Case</u>, 60 ANN. RHEUM. DIS. A226 (2001); filed as Exhibit 34.

Hi Yeon Chung et al., <u>Myasthenia gravis following human papillomavirus</u> vaccination: a case report, 18 BMC NEUROLOGY 222 (2018); filed as Exhibit 35.

<sup>&</sup>lt;sup>10</sup> Setijoso Eddy et al., <u>Myasthenia Gravis: Another Autoimmune Disease</u> <u>Associated with Hepatitis C Virus Infection</u>, 44 DIG. DIS. SCI. 186 (1999); filed as Exhibit 27.

with myasthenia gravis. Pet'r's Br. at 17, citing Frontera. But, this level of abstraction suffers from the same questions as the previous two types of analogies. Why is the flu vaccine like the Covid vaccine? Why is myasthenia gravis like GBS or cerebral venous thrombosis? Neither Mr. Demore, nor Dr. Simpson, nor Dr. Simon connects the dots persuasively. See Herms v. Sec'y of Health & Hum. Servs., No. 19-70V, 2024 WL 1340669, at \*21 (Fed. Cl. Spec. Mstr. Jan. 23, 2024) (stating "Petitioner does not explain how data from other unrelated vaccines could be extrapolated to the vaccines at issue here and accordingly, the data is not persuasive"), mot. for rev. denied, 2024 WL 3837327, at \*10 (ruling that the special master gave "adequate consideration" to literature mostly addressing "different vaccinations, different conditions, or both").

Overall, neither Dr. Simpson nor Dr. Simon have presented a sound and reliable medical theory to explain how the flu vaccine can cause myasthenia gravis. Much like Dr. Tornatore's reports in <u>Dennington</u>, their reports are far too general to be persuasive. <u>See</u> Exhibit 14 at 5, Exhibit 40 at 2, Exhibit 43, Exhibit 44.

In sum, Mr. Demore has not established with preponderate evidence that molecular mimicry is a reliable theory to explain how the flu vaccine can cause myasthenia gravis. This outcome is based upon this case's evidence.

The outcome in Mr. Demore's case---a denial of compensation---is consistent with the result of two relatively recent cases. See Resp't's Br. at 33-34 (bringing forward these cases); Pet'r's Reply at 4-5 (responding to these two cases and adding a third case). Both Smilo, 2023 WL 3918397, at \*37, and Kelly v. Sec'y of Health & Hum. Servs., No. 16-1548V, 2023 WL 3274159, at \*9-10 (Fed. Cl. Spec. Mstr. May 5, 2023), found deficiencies in the theory that a flu vaccine could cause or worsen myasthenia gravis via molecular mimicry. Although these decisions do not constitute binding precedent, Smilo and Kelly are well-reasoned.

By way of contrast, the case Mr. Demore cited in his reply, <u>Francis v. Sec'y of Health & Hum. Servs.</u>, No. 99-520V, 2007 WL 1673512 (Fed. Cl. Spec. Mstr. May 23, 2007), carries less precedential value. <sup>12</sup> Although molecular mimicry was credited as a theory, <u>Id.</u> at \*16-17, <u>Francis</u> was decided before appellate opinions,

<sup>&</sup>lt;sup>11</sup> Jennifer A. Frontera et al., <u>Neurological Events Reported after COVID-19</u> <u>Vaccines: An Analysis of Vaccine Adverse Event Reporting System</u>, 91 ANN. NEUROL. 756 (2022); filed as Exhibit 48.

<sup>&</sup>lt;sup>12</sup> The better practice is for petitioners to cite supporting cases in their primary brief, not the reply brief.

such as <u>W.C.</u>, <u>Caves</u>, and <u>Dennington</u>, suggested that a more comprehensive showing regarding molecular mimicry was appropriate. Moreover, <u>Francis</u> assessed whether molecular mimicry was "a plausible biological mechanism," 2007 WL 1673512, at \*16. This standard is too low a burden. <u>LaLonde v. Sec'y of Health & Hum. Servs.</u>, 746 F.3d 1334, 1339-40 (Fed. Cir. 2014); <u>but see Hoffman v. Sec'y of Health & Hum. Servs</u>, No. 19-111V, 2024 WL 3688477, at \*14 (holding that biologic plausibility is the correct standard). For these reasons, Francis does not influence the outcome of Mr. Demore's case.

#### V. Conclusion

Within about two weeks of receiving a flu vaccination, Mr. Demore developed myasthenia gravis and the short interval between events appears to have led Mr. Demore to assert that the flu vaccine caused his myasthenia gravis. However, the evidence regarding how the flu vaccine can cause myasthenia gravis is lacking in persuasiveness. Thus, despite sympathy for Mr. Demore for his suffering, he cannot receive compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran Christian J. Moran Special Master